

**UNITED STATES PATENT APPLICATION
FOR
FEMALE CLEAN INTERMITTENT CATHETER SYSTEM**

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FEMALE CLEAN INTERMITTENT CATHETER SYSTEM

PRIORITY CLAIM

5 This application claims the benefit of provisional application Serial
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DESCRIPTION

The present invention relates in general to a system and method for
using a female catheter and in particular to a system and method for clean
intermittent female catheterization by a user or health care provider.

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BACKGROUND OF THE INVENTION

It is estimated that urinary catheters are placed in millions of
women each year in the United States alone, either due to some illness,

infection or malfunction or as part of a medical procedure. Care must be taken to clean the catheter site to reduce the risk of nosocomial infection (i.e., an infection that arises due to a procedure for treating a disorder and unrelated to the disorder itself, also referred to as a "hospital infection").

- 5 The most common nosocomial infections are related to or arise from indwelling urinary bladder catheters (i.e., catheters that remain in the urinary tract for a relatively long length of time). The risk of such catheter-related nosocomial infections can be reduced using strict aseptic techniques (i.e., using gloves, disinfectants, antibacterial soaps, etc.)
- 10 when handling the catheter. Moreover, the risk of infection can further be reduced by only using a catheter intermittently rather than leaving the catheter in place for any length of time. Intermittent use of the catheter in conjunction with clean techniques helps to reduce the risk of catheter-related nosocomial infections and is, moreover, a far more attractive
- 15 alternative for bladder evacuation to most patients who are candidates for the procedure.

- Using a urinary bladder catheter under aseptic conditions in a hospital is routine. However, current medical practice emphasizes getting the patient ambulatory (and out of the hospital) as soon as possible.
- 20 Consequently, catheterizations or catheter insertions are performed at home by nonprofessionals. These nonprofessionals must be taught clean

techniques. However, no know comprehensive devices, apparatus or methods exist for teaching clean techniques or for facilitating such home catheter use for women.

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SUMMARY OF INVENTION

The present invention provides a method and system for intermittent catheterization by the patient herself, the patient's caregiver, or a health care provider. The present invention contains apparatus for facilitating at least one catheterization and comprises: (I) at least one female catheter; (II) antibacterial soap; (III) lubricant; (IV) step-by step instructions; and (V) a container, where the above named items are positioned inside the container. It should be appreciated that the present invention may only be used on the order of a physician.

Preferred embodiments of the system contain sufficient apparatus for one month of catheterizations or catheter insertions (approximately 3 to 4 times a day), the antibacterial soap is in liquid form, the lubricant is in gel form, the step-by-step instructions are written in English and Spanish, although other languages (e.g., Polish, French and German for example) are contemplated. One preferred embodiment of the system includes a contents map identifying the contents and the positions of the contents, along with zipper bags, a fanny pack and a protective underpad.

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In a more preferred embodiment of the system, the system contains apparatus for at least one month of catheterizations as provided previously and comprises: (I) four intermittent female catheters; (II) thirty-five disposable wipes; (III) one protective underpad; (IV) antibacterial liquid soap; (V) one tube of lubricant; (VI) a mirror; (VII) step-by-step instructions; (VIII) clinician step-by-step instructions or self-care documentation; and (IX) a box, wherein the above-named items are positioned inside the box.

The method for intermittent catheterization comprises evacuating the bladder using the apparatus of the present invention in accordance with the detailed step-by-step instructions provided in the system. In a preferred embodiment, the method which is discussed in further detail below generally includes: (I) preparing for intermittent female catheterization; (II) preparing the female catheter; (III) inserting the female catheter; (IV) draining the bladder; (V) recording and disposing of the drainage; and (VI) cleaning and storing the apparatus of the present invention.

The present invention further includes a patient education system for educating users in performing intermittent female catheterization. Specifically, the system includes a system and a black and white copy of the step-by-step instructions without illustrations (referred to herein as

self-care documentation). An instructor (i.e., a doctor, nurse, clinician or other medical professional) uses the self-care documentation to educate the user in performing an intermittent female catheterization, preferably using the system of the present invention. The medical professional then

5 keeps the self-care documentation documenting that the user was educated in performing female catheterization.

It is therefore an object of the present invention to provide a system and method for intermittent female catheterization.

It is a further object of the present invention to provide detailed

10 instructions for intermittent female catheterization using the contents of a self-care system.

An additional object of the present invention is to provide self-care documentation to be used by a medical professional in instructing users in the use of the self-care system.

15 Yet an additional object of the present invention is to provide a patient education system for educating users in performing intermittent female catheterization using the system.

Other objects, features and advantages of the invention will become apparent from the following detailed disclosure, taken in

20 conjunction with the accompanying sheets of drawings, wherein like numerals refer to like parts, components and processes.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective view of the system of the present invention;

Fig 1A is a top plan view of the contents map of the present
5 invention;

Figs. 2A and 2B are top plan views of the step-by-step instructions
in English of the system of the present invention;

Figs. 3A and 3B are top plan views of the step-by-step instructions
in Spanish of the system of the present invention;

10 Fig. 4 is a top plan view of the self-care documentation in English
used by a medical professional for documenting that the users are
instructed in the use of the system of the present invention; and

Fig. 5 is a top plan view of the urine record card.

DETAILED DESCRIPTION OF THE INVENTION

It should be appreciated that the figures include one or more of the following trademarks which may be used by the assignee of this application: (a) CAREGUIDE; and (b) CAREGUIDE and DESIGN. It should be appreciated that these trademarks are not part of the present invention.

The present invention is for a system 10 and method for intermittent catheterization of a patient. The user may be the patient herself, the patient's caregiver, an in-home care provider or a healthcare provider which, for brevity, are referred to herein as the "user." The system 10 provides apparatus needed for in-home catheterization.

In general, the intermittent catheterization system 10 contains at least: (I) infection prevention devices (gloves, disposable wipes, zipper bags, alcohol gel (i.e., a waterless cleanser), soap, and protective underpads); (II) insertion devices (female catheter, mirror and lubricant); (III) recording devices (urine record card and collection basin) and (IV) information devices (step-by-step instructions, contents map and self-care documentation) among other items.

More specifically, as illustrated by Figs. 1 and 1A, the intermittent catheterization system 10 of the present invention comprises: (I) gloves

12; (II) a collection basin 14; (III) disposable wipes or washcloths 16;
(IV) protective underpad 18; (V) antibacterial soap 24; (VI) lubricating gel
20; (VII) female intermittent catheter 22; (VIII) clean and used zipper bags
26 and 28 respectively; (IX) a mirror 29; (X) step-by-step instructions 34
5 (not shown in Fig. 1); (XI) self-care documentation 44 (not shown in Fig.
1); and (XII) a container or box 40. It is contemplated that the system 10
may also include a contents map 42 which identify the contents of the
container 40 and their position, and one or more waste bags.

In one preferred embodiment, the container 40 contains gloves 12,
10 a plastic collection basin 14 with graduated markings, disposable wipes
16, protective underpads 18, single doses of lubricating gel 20, female
catheters 22, antibacterial liquid soap 24, clean catheter zipper bags 26, a
used catheter zipper bag 28, alcohol gel 30, a urine record card 32
(illustrated in Fig. 5), a lubricating gel tube 20a, a fanny pack 38, a mirror
15 29, a travel wipe pack 46, self care documentation 44, and step-by-step
instructions 34 as revealed by Figs. 1, 2A and 2B, and 3A and 3B. It
should be appreciated that system 10 could be provided to the patient in a
box, tray, bag, container or any other suitable content holder device 40. A
box is preferred as it is strong enough to protect the contents of the
20 system 10 and yet is suitable for shipping and storing. If a bag, tray,

container or other content holding devices are used, a contents map 42 may or may not be included with system 10.

In one preferred embodiment, a urologist, clinician or other medical professional provides system 10 to the user, although it is contemplated
5 that the user could obtain system 10 through other means but only under a medical professional's care. System 10 includes extremely detailed and specific step-by-step instructions 34 as illustrated in Figs. 2A and 2B that the user uses with the intermittent female catheterization system 10 (specific step-by-step instructions in Spanish are illustrated in Figs. 3A and
10 3B). System 10 also includes the self-care documentation 44 the medical professional uses to document or record the instructions provided to the user in the use of the intermittent female catheterization system 10 as illustrated in Fig. 4. A difference between the two sets of instructions is that the instructions in Fig. 4 are in black and white and include
15 acknowledgment sections 45A and 45B, while the instructions in Figs. 2A and 2B are illustrated in color (not shown) for ease of use by the patient. It is also contemplated that system 10 could include an instructional video, training the user in the use of the system 10.

In one preferred embodiment, system 10 includes sufficient
20 apparatus for one month of catheter insertions, the antibacterial soap 24 is in a liquid form, the lubricant 20 is provided in a gel or ointment form, and

the step-by-step instructions 34, and the contents map 42 (if included) are written in English. While not necessary, one preferred embodiment also includes one or more gloves 12, disposable wipes 16 and a protective underpad 18. It should be appreciated that a user could order a refill of

5 the disposable apparatus of the present invention using an order form provided with the apparatus of the present invention.

In a more preferred embodiment of the system, system 10 includes apparatus for at least one month of catheterization and comprises: (I) 10 gloves 12; (II) one collection basin 14; (III) 35 disposable wipes 16; (IV) 3 protective underpads 18; (V) 10 single tubes of lubricating gel 20a; (VI) 4 female intermittent catheters 22; (VII) antibacterial liquid soap 24; (VIII) 4 clean catheter zipper bags 26; (IX) one used catheter zipper bag 28; (X) 4 oz of alcohol gel 30; (XI) one urine record card 32; (XII) one lubricating gel tube 36; (XIII) a fanny pack 38; (XIV) a mirror 29; (XV) one pack of travel wipes 46; (XVI) self-care documentation 44; (XVII) detailed step-by-step instructions 34; (XVIII) a contents map 42; and (XIX) container or box 40 wherein the above-named items are positioned inside the box 40.

The system 10 includes apparatus necessary for intermittent female catheterization in accordance with the method. The system 10 organizes the apparatus in an easy-to-find format. The step-by-step instructions 34 indicate when an item is first required during the method

and should be removed from the container 40 (preferably using red text to indicate when an item is first required). Using the step-by-step instructions 34 and the contents map 42, users can easily identify when each item is required in the method and readily find it in the container 40.

- 5 It should be appreciated that the items and step-by-step instructions 34 could be color coded and/or use icons making identifying each item even easier. For example, the antibacterial soap 24 could be identified by a bubbles icon and blue coloring corresponding to a bubbles icon and blue color in the step-by-step instructions 34.
- 10 The method of the present invention generally comprises using the system 10 in accordance with the detailed step-by step instructions 34. In a preferred embodiment, the method generally includes: (I) preparing for intermittent female catheterization; (II) preparing the female catheter; (III) inserting the female catheter; (IV) draining the bladder; (V) recording and disposing of the drainage; and (VI) removing the female catheter and cleaning and storing the apparatus.
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Preparing for Intermittent Female Catheterization (Step I)

The first step of the method of the present invention, is illustrated by Figs. 2A and 2B and includes preparing and caring for the female catheterization site. Preparing and caring for the female catheterization

5 site includes: (I) obtaining a clean, fresh towel; (II) washing using the antibacterial liquid soap 24 and warm water, and using the clean towel for drying; (III) finding a safe, flat, uncluttered, solid surface; (IV) putting on the gloves 12 only if the catheterization is being performed by a user other than the patient which includes: (a) taking a pair of gloves 12 out of the

10 box 40; and (b) putting them on; (V) preparing the surface which includes: (a) obtaining two clean, fresh paper towels; (b) opening the two paper towels; (c) placing the opened paper towels on the surface; (d) taking a protective underpad 18 out of the box 40; (e) opening the protective underpad 18; and (f) placing the opened protective underpad 18 under the

15 patient's buttocks and near the opened paper towels; (VI) cleaning the catheter site which includes: (a) taking a paper wash cloth or disposable wipe 16 out of the box 40; (b) taking the container of antibacterial soap 24; (c) squeezing out approximately one dime's worth (i.e., about one or two drops) of soap 24 onto the center of the wipe 16; (d) creating a lather on

20 approximately one half of the wipe 16; (e) leaning back in a frog-leg position; (f) taking out the folding mirror 29; (g) folding the mirror 29 so that

it stands by itself; (h) adjusting the mirror 29 to view the catheterization site including the opening of the urethra; and (i) gently washing the site using the wipe 16, the soap 24 and warm water, washing the site from the top to the back; (j) washing the site three times, using a clean area of the 5 wipe 16; and (k) rinsing using the other half (unlathered half) of the wipe 16; (VII) throwing the wipe 16 away; (VIII) washing using the antibacterial soap 24 as described previously. It should be appreciated that step (VIII) can be skipped if the user is wearing gloves 12.

10 Preparing The Female Catheter (Step II)

The second step of the method as illustrated includes inserting the female catheter 22 into the urethra. Inserting the female catheter 22 includes: (I) taking a female catheter 22 out of the box 40; (II) laying the catheter 22 on the paper towels; (III) take the collection basin 14 out of the 15 box 40 and placing it near the paper towels; (IV) applying the lubricating gel 20 which includes: (a) taking the lubricating gel tube 20 out the box 40; (b) flipping open the cap of the tube 20; (c) squeezing 3 inches of lubricating gel 20 onto the catheter 22 starting at the tip, being careful not to touch the catheter 22 with the tube 20; (d) rolling the catheter 22 in the 20 lubricating gel 20 so that all sides are covered; (e) lifting the catheter 22 away from the paper towel and laying the wide end of the catheter 22 in

the collection basin 14; and (f) moving the basin 14 close to the user so that the wide end of the catheter 22 is not accidentally pulled out of the basin 14.

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Inserting the Female Catheter (Step III)

The third step of the present invention comprises inserting the catheter 22 into the urethra. Inserting the catheter 22 comprises: (I) sitting on the underpad 18; (II) separating the labia with one hand; (III) picking up the catheter 22 near the tip with the other hand, keeping the other end in 10 the basin 14; (IV) having the patient taking a deep breath; (V) gently inserting the tip of catheter 22 into the urethra; (VI) pushing backward and upward until a bit (i.e., at least a drop) of urine appears; and (VII) slowly pushing the catheter 22 in one inch more.

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Draining the Bladder (Step IV)

The fourth step of the method comprises draining the site (i.e., the bladder) forming a drainage. Draining the catheter site using the catheter 22 comprises: (I) placing or holding the basin 14 in proximity to the widened (i.e., uninserted) end of the catheter 22; (II) making sure the wide 20 end of the catheter 22 is in the basin 14; (III) holding the catheter 22 in place and emptying the bladder into the basin 14; (IV) making sure the urine is running into the basin 14; (V) pushing down on the bladder,

making sure it is empty; and (VI) slowly pulling the catheter 22 out when the bladder is empty (i.e., the urine stops).

Recording and Disposing of the Drainage (Step V)

5 The next step of the method includes recording and disposing of the drainage. This step includes: (I) recording the amount of the drainage, including: (a) measuring the drainage level using the markings on the basin 14; (b) writing this amount on the urine record card 32 illustrated Fig. 5; (c) noticing the color and smell of the drainage; and (d) recording the 10 color and smell (and anything else to tell the doctor) on the urine record card 32; and (II) disposing of the drainage, preferably emptying the basin 32 in a toilet.

Cleaning and Storing the Apparatus (Step VI)

15 The next step includes completing the intermittent catheterization in accordance with the method. Completing the catheterization includes: (I) cleaning the used catheter, which includes: (a) washing the used catheter 22 with two or three drops of the antibacterial soap 24 and warm water; (b) holding the catheter 22 under running tap water, rinsing it well 20 inside and out; (c) shaking the catheter 22 gently several times to remove any excess water; and (d) placing the catheter 22 on a clean, fresh paper towel to air dry; (II) removing any gel left on the female catheterization site

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using toilet paper or other soft wipe; (III) cleaning the basin 14, which includes: (a) washing the basin 14 using two drops of antibacterial soap 24 and warm water; (b) rinsing the basin with warm water; and (c) placing the basin 14 on clean, fresh paper towel to air dry; (IV) closing the cap on 5 the lubricating gel tube 20; (V) placing all the apparatus back in the box 40; (VI) placing the dry catheter 22 inside a clean catheter zipper bag 26, zipping it closed; (VII) placing the clean catheter zipper bag 26 in the box 40; (VIII) placing the dry basin 14 in the box 40; (IX) placing the underpad 18 in the box 40 if clean, or throwing it away if dirty; and (X) disposing of 10 the wipe 16 and the paper towels.

It should be anticipated that the patient is not bed bound, but able and willing to get around. One preferred embodiment of the present invention includes a fanny pack 38 that enables users to travel. As illustrated in Figs. 2A and 2B, method provides that, for every four hours of 15 travel, the fanny pack 38 should include: (I) one clean catheter 22 in the clean catheter zipper bag 26; (II) one packet of lubricating gel 20a; and (c) two clean paper towels. The fanny pack 38 should also include the pack of pre-wet travel wipes 46, the used catheter zipper bag 28, and the alcohol gel 30 for handwashing in case water is not available.

20 When catheterization is required, the user should find a place (preferably a bathroom) and follow Steps I-VI above, using clean paper

towels for a clean work surface. After removing the catheter 22 in Step V, the user should rinse it off if possible and store it in the used catheter zipper bag 28, placing the bag 28 in the fanny pack 38. The user should then wash as described above in Step I. The used catheters may be
5 cleaned completely upon returning home.

The present invention includes teaching or instructing the user in the use of system 10. System 10 includes a set of extremely detailed, step-by step instructions 34, as illustrated in Figs. 2A, 2B, 3A and 3B and self-care documentation 44 illustrated in Fig. 4.

10 Federal, state and local regulatory agencies require that the medical professional maintain complete records, including records to training provided to individuals. The medical care professional uses the self-care documentation to document providing the instructions to the patient or user on the use of the method and system 10 as illustrated in
15 Fig. 4. The instructions enables the medical care professional to ensure that the training is complete, providing a signature box or acknowledgement areas 45A and 45B for the user to indicate that they received and understand the instructions. This documentation 44 is maintained by the clinician or a medical provider as part of the clinical
20 record, where they may be used for accreditation and/or legal purposes.

The present invention further contemplates a patient education system for educating users in performing intermittent female catheterization. The system includes the system 10 and the self-care documentation 44. The present invention is only used on the order of a physician. An instructor (i.e., a doctor, nurse, clinician, other medical profession, or any individual trained to educate users in performing female catheterization) uses step-by-step instructions 34 or 44 to teach the users to perform a female catheterization, preferably using the system 10. The instructor takes the user through the process of performing a female catheterization step-by-step, and may even demonstrate specific procedures using specific items in the system 10. For example, it is contemplated that the instructor could demonstrate how to apply lubricating gel to the catheter 22, clean the catheter 22, record drainage, etc. It should be appreciated that the instructor could use a model to demonstrate how to insert the female catheter 22, drain the bladder and remove the catheter 22.

It should be appreciated that the system 10 may contain sufficient apparatus for one or more catheter insertions; for example, apparatus for two, three, four or more months of catheter usage are contemplated. Further, it should be appreciated that refills for system 10 may be

provided. In a preferred embodiment, a reorder form may be provided in system 10.

While the present invention has been described in connection with what is presently considered to be the most practical and preferred 5 embodiments, it is to be understood that the invention is not limited to the disclosed embodiments, but on the contrary is intended to cover various modifications and equivalent arrangements included within the spirit and modifications and equivalent arrangements included within the spirit and scope of the claims. It is thus to be understood that modifications and variations in the present invention may be made without departing from 10 the novel aspects of this invention as defined in the claims, and that this application is to be limited only by the scope of the claims.